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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/421,506 | 10/19/1999 | SALVATORE ALBANI | 246/285 | 4242 |

7590

04/09/2004

DANIEL M CHAMBERS
BIOTECHNOLOGY LAW GROUP
658 MARSOLAN AVENUE
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EXAMINER

EWOLDT, GERALD R

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 04/09/2004

31

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--|--|--|
| Office Action Summary | Applicati n No. 09/421,506 | Applicant(s) ALBANI, SALVATORE | |
| | Examiner G. R. Ewoldt, Ph.D. | Art Unit 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2003 and 30 September 2003.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 383-391 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 383-391 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>pet. dec.</u> |

DETAILED ACTION

1. The request filed on 9/30/03 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/421,506 is acceptable and a CPA has been established. An action on the CPA follows.

2. Applicant's election without traverse of Group I, in the paper filed 6/04/03, is acknowledged. Applicant has canceled all pending claims and replaced them with Claims 383-391. Claims 383-384 and 387-391 read on the elected invention. Claim 385 reads on the invention of Group II and Claim 386 reads on the invention of Group III. Upon further consideration Groups II and III are hereby rejoined.

3. All pending Claims, 383-391, are being acted upon.

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because it does not include the citizenship of the Inventors.

A new declaration properly executed by all inventors is required. See MPEP §§ 608.04(b).

5. The Abstract and the Title are objected to because they do not adequately describe the claimed invention. Applicant is advised that an Abstract and Title commensurate in scope with the invention of the instant claims are required. See MPEP 608.01(b).

6. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

A) the invention of Claim 383, a method of identifying a T cell specific for an antigen of interest,

B) the invention of Claim 383, including an MHC component,

C) the invention of Claim 387, employing a biological sample consisting of whole blood or blood cells,

D) the invention of Claim 390, wherein the label is bound to ... a cholesterol molecule,

have no antecedent basis in the specification. The specification must be amended to include said limitations. Note, regarding B) the specification can support "an MHC:Ag component".

7. Applicant is advised that, due to their excessive number, the amendments to the specification, filed 6/29/01 and 8/08/01, have not been entered. Because an excessive number of corrections and replacement paragraphs would be required to correct the deficiencies of the instant specification, a substitute specification excluding claims is required pursuant to 37 CFR 1.125(a).

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 383-391 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically:

A) In Claims 383, in part iii., "a GM-1 ganglioside molecule" would more properly be "said GM-1 ganglioside molecule".

B) In Claim 389 "wherein artificial antigen presenting cell" would more properly be "wherein said artificial antigen presenting cell".

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claim 388 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Under *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed.

There is insufficient written description to show that Applicant was in possession of the group consisting of a "peptide, a peptide derived from a recipient of a graft, a cancer cell-derived peptide, a peptide derived from an allergen, a donor-derived peptide, a pathogen-derived molecule, a peptide derived by epitope mapping, a self-derived molecule, a self-derived molecule that has sequence identity with a pathogen-derived antigen", recited in the claim. As the terms encompass an essentially unlimited genus, one of skill in the art would conclude that the specification fails to adequately describe said genus given that no examples of the various types of "antigens" are disclosed. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

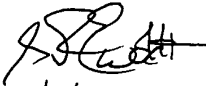
Please Note: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information

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about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600


4/7/04
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER



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| ART UNIT | PAPER NUMBER |
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DATE MAILED:

The decision on the petition filed in the above entitled application is as follows:

☐ Delay in Prosecution Held Unavoidable (35 U.S.C. 133),
Petition Granted _____

☐ Delayed Payment of Issue Fee Accepted (35 U.S.C. 151),
Petition Granted _____

☒ Petition Granted *The petition for color photographs under 37 CFR 1.84(b) filed 10/19/99 is hereby granted.*

☐ Petition Denied _____

☐ Petition Dismissed _____

By direction of the Deputy
Assistant Commissioner for Patents

Christina Chan
CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600